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**CERTIFICATE OF INTEREST OF SOFT GEL**

Counsel for Plaintiff/Counterclaim Defendant-Cross Appellant Soft Gel Technologies, Inc., certifies the following in accordance with Federal Circuit Rule 47.4:

1. The full names of every party or amicus represented by the undersigned are:

Soft Gel Technologies, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by the undersigned is:

The real party in interest is named in the caption.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by the undersigned are:

Soft Gel Technologies, Inc. is wholly owned by Kenko Corporation.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by the undersigned in the trial court or agency or are expected to appear in this court are:

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**CERTIFICATE OF INTEREST OF NOW FOODS**

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1. The full names of every party or amicus represented by the undersigned are:

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2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by the undersigned is:

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3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by the undersigned are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by the undersigned in the trial court or agency or are expected to appear in this court are:

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## **ABBREVIATIONS AND CITATIONS**

Citations to the Appendix are in the form A-1234, where page “1234” of the Appendix is the cited page. Where appropriate, line numbers for given pages are cited as A-1234:7-10, where lines 7 to 10 of page 1234 are cited.

The District Court’s findings of fact and conclusions of law on inequitable conduct ruling are contained in the addendum to JFI’s brief at A-36 to A-48.

U.S. Patent No. 7,588,786 is referred to as the ‘786 patent. Citations to the patent may include specific columns and lines, such as 1:46-52, where column 1, lines 46 to 52 are cited.

Soft Gel Technologies, Inc. is referred to as Soft Gel.

NOW Health Group, Inc. d/b/a NOW Foods is referred to as Now Foods.

Jarrow Formulas, Inc. is referred to a JFI.

Mansoor Khan, a named inventor on the ‘786 patent, is referred to as Khan.

Sami Nazzal, a named inventor on the ‘786 patent, is referred to as Nazzal.

JFI’s expert witness, Robert Williams, is referred to as Williams.

Texas Tech University is referred to as TTU.

The Texas Tech University IP Office is referred to as the TTU IP Office.

K. Lance Anderson, of the TTU IP Office, is referred to as Anderson.

### **STATEMENT OF RELATED CASES**

No other appeals in or from the same civil actions or proceedings in the lower court were previously before this or any other appellate court. There are no cases known to counsel for Cross Appellants to be pending in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeals.

## **THE ISSUES PRESENTED FOR REVIEW**

1. Noninfringement: Whether the District Court erred in granting summary judgment of noninfringement where the patent owner failed to present evidence that the accused products met the District Court’s unchallenged construction of the melting point reduction limitation of the asserted claims.

2. Evidence: Whether the District Court abused its discretion in excluding the expert declarations of Williams and Nazzal, which were untimely under the Court’s schedule for expert disclosures.

3. Claim Construction: Whether the District Court erred in not giving the term “eutectic-based” its ordinary meaning, where it was used to distinguish the prior art, and the public record ascribes no special, non-ordinary meaning to the term.

4. Unenforceability:

a) Whether the District Court erred as a matter of law in applying an overly restrictive test for specific intent to deceive;

b) Whether the District Court erred as a matter of law by applying a standard which required it to credit an unsupported “alternative inference;”

c) Whether the District Court erred as a matter of law by applying a standard which did not require it to assess the relative strength of the competing “alternative inferences;”



d) Whether the District Court's finding of a reasonable alternative inference was clearly erroneous; and

e) Whether the District Court's finding of no inequitable conduct was an abuse of discretion.

## **STATEMENT OF THE CASE**

### **I. PROCEDURAL HISTORY.**

JFI sued Soft Gel's customer, NOW Foods, alleging infringement of the '786 patent. (A243-72.) The accused products included products which Soft Gel manufactured and sold to NOW Foods. (A166 at ¶ 8.) NOW Foods answered denying infringement. (A274-276.) Soft Gel sued JFI, seeking declaratory judgments that the '786 patent was un infringed, invalid and unenforceable. (A164-95.) The District Court consolidated the actions. (ECF No. 40.) After the close of discovery, Soft Gel filed a motion for summary judgment of noninfringement and invalidity. (A281-283.) NOW Foods joined in Soft Gel's motion, as the only remaining accused products sold by NOW Foods were sourced from Soft Gel. (ECF No. 105.) While Cross Appellants refer to the motion as Soft Gel's, the District Court's summary judgment applies equally to both Soft Gel and NOW Foods. This is the joint brief of Soft Gel and NOW Foods as appellees and as cross appellants with respect to the construction of "eutectic-based." Because NOW Foods did not assert inequitable conduct in the District Court, that portion of the cross appeal is brought and briefed by Soft Gel only, although unenforceability would be an alternative basis for affirming the judgment of no liability as to NOW Foods.

## II. THE '786 PATENT.

The '786 patent addresses the problem of oral administration of ubiquinone (also referred to in the patent as Coenzyme Q10 or CoQ<sub>10</sub>.) The patent teaches that ubiquinone has “poor water solubility.” (A-62, '786 patent, 1:46.) Accordingly, traditional methods for delivering ubiquinone involved dissolving it in fixed oils or triglycerides, and subsequently blending with suitable solubilizing agents. (A-62 '786 patent, 1:56-59.) Because of ubiquinone's limited solubility in these oils, however, the patent discloses that these traditional methods result in “low drug loading” and “suffer from irreversible precipitation of the active ingredient,” i.e., ubiquinone. (A-62 '786 patent, 1:55-62.)

The patent states that it overcame the difficulty of dissolving ubiquinone by reducing the melting point of ubiquinone, so that the ubiquinone becomes a liquid at or below 37° C: “Due to the limited solubility of CoQ<sub>10</sub> in fixed oils and triglycerides, the melting point depression method using essential oils provides an attractive alternative for the preparation of an emulsified formulation.” (A-62 '786 patent, 6:57-60.) In arguing for patentability, the '786 applicant asserted that “[a]s is widely known by those of skill in the art, CoQ<sub>10</sub> is extremely insoluble even in organic solvents that dissolve most quinones.” (A-1823.) Melting point reduction was presented as the alternative to dissolving: “To overcome the foregoing problems, a eutectic-based semisolid self-nanoemulsified drug delivery system

(SNEDDS) was formed as an alternative to conventional self emulsifying vehicles.” (A-62 ‘786 patent, 2:32-35.)

The ‘786 patent itself cautions that the presence of other ingredients can prevent a melting point reduction and that one must consider all the ingredients of the mixture to determine whether a eutectic or melting point reduction is achieved. The patent explains that “[e]ssential oils, however, should be effective as eutectic agents in the presence of other liquid excipients.” (A-65 ‘786 patent, 7:2-3.) The patent describes an experiment in which “[f]our essential oils. . . were evaluated for their eutectic efficacy in the presence of other formulation excipients.” (A-65 ‘786 patent, 7:6-9.) The results showed that the presence of other ingredients can prevent a eutectic effect and a melting point reduction. (A-65 ‘786 patent, 7:14-16, and Table 2 (noting that “N/A” indicates that the mixture did not melt in 24 hours).)

Similarly, during prosecution, the applicant – represented by JFI’s counsel in this case – emphasized that one must combine all the ingredients of the mixture and “assay[] for a reduction in the melting point temperature.” (A-1838-1839.) The file history explained, as did the written description, that one must consider all the ingredients of the mixture as each ingredient can impact the properties of the mixture: “As taught in the present specification, a eutectic composition is

**dependent on the relative proportions of all ingredients in the mixture.”** (*Id.* (underscore in original; bold emphasis added).)

During prosecution, the applicant emphasized that empirical testing and assays were necessary to determine whether there was a melting point reduction: “A[n] eutectic effect cannot be predicted, *a priori*, but is empirically determined by mixing two or more ingredients and **assaying for a reduction in the melting temperature.**” (A-1828 (italics in original; other emphasis added).) The applicant also distinguished the prior art, arguing that eutectic mixtures were so unpredictable that even if the prior art showed a eutectic mixture for another quinone, it did not disclose that a eutectic mixture could be obtained with a different quinone (*i.e.*, ubiquinone): “As is well known in the art, eutectic mixtures cannot be predicted, and therefore, generally **must be identified empirically.**” (A-1822 (emphasis in original).)

JFI’s expert, Williams, agreed with statements made in the ‘786 patent and file history that melting point reductions are unpredictable and must be determined by chemical testing and assays that take into account all ingredients in a mixture. Williams admitted that “the eutectic effect does not necessarily and inevitably occur merely from the presence of two ingredients,” such as “essential oil and ubiquinone in a mixture.” (A-539:2-13.) Further, Williams admitted that “the eutectic effect does not necessarily occur merely because CoQ<sub>10</sub> and essential oils

are present in equal amounts in a mixture.” (A-539:14-21.) Williams agreed that “a eutectic composition is dependent on the relative proportions of all ingredients in the mixture.” (A-539-540.) Williams also testified that one would need to perform experiments and tests to determine whether a composition exhibited a melting point reduction. (A-518-520.)

### **III. THE WILLIAMS REPORTS & DECLARATIONS.**

In deciding the summary judgment motions, the District Court considered the opinions in Williams’ February 10, February 17 and March 15, 2012 expert reports. (A-369-401; A-425-450; A-452-473.) The District Court excluded the opinions contained in Williams’ May 4 and May 25, 2012 Declarations. (A-29.)

#### **A. Williams’ February 10, February 17 And March 15, 2012 Reports Provided No Infringement Opinion Based On The Court’s Unchallenged Construction Of “Melting Point” And “Melting Point Reduction.”**

Williams’ February 10, February 17 and March 15 Reports do not contain any opinion on infringement based on the unchallenged ordinary meaning construction of “melting point” and “melting point reduction” that was adopted by the District Court: “the Court construes ‘melting point’ to mean ‘the temperature at which a chemical agent has a transition from solid to liquid due to the application of heat’ and construes ‘reduc[tion of] the melting point’ to require ‘a change or modification of the physical properties of ubiquinone; i.e., depression of its melting point,’ and not merely dissolution.” (A-21.)

JFI does not challenge the District Court's claim construction on appeal. Indeed, Williams conceded the ordinary meaning of melt. He testified that "outside this context [the context of the '786 patent], 'melt' would be understood by a person of ordinary skill in the art to – to mean a phase transition from a solid to a liquid." (A-489-490.) He also testified that the phase transition occurs through the application of heat. (A-494-495.)

Williams' opinions through March 15, however, were not based on the unchallenged ordinary meaning construction of "melt" and "melting point reduction" adopted by the District Court. Instead, they were based on an improper construction that "melt" was synonymous with "dissolve." Specifically, Williams stated in his February 10 Report that "the person of skill . . . would have understood that a eutectic mixture or eutectic-based system, as described and claimed by the '786 patent, is a system in which the melting point of the ubiquinone in the composition is reduced to 37° C. . . or below when solubilized (i.e., dissolved) with a sufficient amount of a volatile essential oil. The '786 patent demonstrates that a eutectic effect (i.e., reduction of ubiquinone's melting point to 37° C or below) is observed when ubiquinone is mixed with a sufficient amount of a volatile essential oil." (See A-380-381 ¶ 19.) Williams' February 17 Report contains identical language. (A-434 ¶ 17.)

Williams made the claim construction underlying his opinions even clearer in his March 15 Report, stating: “the specification and file history. . . indicate that the inventors use the term ‘melting’ interchangeably with dissolution or solubilization. \* \* \* [T]he inventors use the term ‘melting’ to describe the process of CoQ<sub>10</sub> being solubilized or dissolved by a volatile essential oil.” (A-465-466 ¶ 27.) While the March 15 Report addressed the issue of invalidity, it is black letter law, that claims must be construed the same for infringement as for invalidity. Yoon Ja Kim v. ConAgra Foods, Inc., 465 F.3d 1312, 1324 (Fed. Cir. 2006).

Williams emphasized this claim construction in his deposition: “In my opinion – and I state that in my – the third report, March report – to one of skill in the art in this context, ‘melt’ is used interchangeably with ‘dissolve’ or ‘solubilize.’ It means – this would be read – in the context it would mean that the ubiquinone is dissolving or being dissolved at – at that temperature in one of those essential oils.” (A-489:18-24.)

In fact, Williams’ opinions were based on a construction that essentially struck “melt” and “melting point” from the claim:

“Well, I don’t really know why they use the term ‘melt.’ So I’m telling you what my opinion is as – as I think one of skill in the art would understand it, its meaning they are – they’re adding this CoQ<sub>10</sub> in this particular example with one of these volatile essential oils, they heat it to 37 degrees C. If you increase the heat it should increase the rate of dissolution of the solid in that liquid. They refer to it as



melting. I think, again, one of skill in the art would understand that to be dissolving in that liquid. So – but I – I don’t know why they used the word ‘melt.’”

(A-491-492.) In effect, Williams took the position that the claim was wrong to refer to melting, when the ubiquinone was actually dissolving.

**B. Williams’ Opinions In His February 10, February 17 And March 15 Reports Were Not Based On Any Chemical Testing Or Assays Taking Into Account All Ingredients Of The Accused Products.**

Despite the clear statements in the patent and file history, with which he agreed, Williams did not – at any time – perform any chemical testing or assays to determine whether the mixtures in the accused products generate a melting point reduction. (A-523-524.) He did no testing on the accused products whatsoever. (Id.) In fact, he never saw an actual example of any of the accused products. (A-524.) In addition, despite the clear teachings of the patent and the file history, and his own agreement with those teachings, Williams did not take into account all of the ingredients of the accused products. (A-537.)

Instead of performing testing, Williams “predicted” a melting point reduction. Williams relied on certain Soft Gel advertisements stating that certain products are “Crystal-Free” and “100% Solubilized,” and asserted that the advertisement stated “that d-limonene is directly responsible for solubilizing (i.e., dissolving) the ubiquinone.” (A-382 ¶ 24; A-386 ¶ 32.) But the mere fact that a composition is in solution or crystal-free does not suggest there was a melting

point reduction. Williams never testified that melting was the only way to get ubiquinone into solution. In fact, he testified that ubiquinone would be dissolved in essential oil, not melted. (A-491-492.)

Williams also stated in his February 10 Report that he looked at Formulation Cost Sheets and concluded that the amounts by weight of ubiquinone and d-limonene used in these formulations would be “within the eutectic range as described by the ‘786 patent.” (A-383 ¶ 26.) The “Formulation Cost Sheets,” however, do not even identify the ingredients in the accused products. They simply provide ingredient codes, like “MI-00190” and amounts. (See A-1857-1858; A-532:5-13.) Williams could not explain how the ingredient codes on the Formulation Cost Sheets could be used to identify all the ingredients of the product. (A-533-534; A-538.) He could not even say what all of the ingredients of the accused products were. (*Id.*) JFI relies on Soft Gel’s Master Formulation Sheets in an effort to match those codes up to actual ingredients, but at the time he issued his reports in this case, Williams had not even looked at the Master Formulation Sheets which identify the actual ingredients of the accused products. (A-530-531.) Nor does JFI identify any evidence to support its effort to match up codes to ingredients. In fact, the codes on the Formulation Cost Sheets are different from those on the Master Formulation Sheets, and JFI has identified no testimony from a knowledgeable witness to match them up. JFI’s argument about

matching codes, made for the first time on appeal, is devoid of any evidentiary support.

Williams' February 10 Report does not explain, or provide a basis for, his statement that the amounts of ubiquinone and d-limonene in the accused products would be "within the eutectic range as described by the '786 patent." (A-383 ¶ 26.) At his deposition, Williams testified that he determined, through means that he could not recall, which ingredient codes corresponded to ubiquinone and d-limonene. (A-533:7-15.) Then, he determined the ratio of ubiquinone and d-limonene in the product by weight. (A-535:5-18.) Following this, he looked at Figure 4 of the '786 patent, and the line purporting to show the melting point of mixtures of ubiquinone and lemon oil. (*Id.*) If Figure 4 purported to show that the specified ratio of ubiquinone and lemon oil melted below 37° C, then Williams assumed that a binary mixture of ubiquinone and d-limonene would also melt below 37° C. (A-536-537.) It was undisputed, however, that Figure 4 of the '786 patent pertains to binary mixtures only, while the accused products are not a binary mixture. It was undisputed that each accused product contains more than two ingredients. (A-1857.)

Williams, at one point, candidly admitted that he did not take all the ingredients of the mixture into account:

Q: So you didn't take into account the other ingredients?

A: I think I didn't. I think I didn't.

(A-537.) Williams admitted that because Figure 4 of the '786 patent pertains to binary mixtures, in relying on Figure 4 he would have considered only a binary mixture of ubiquinone and d-limonene and not any of the other ingredients of the accused products:

Q: Okay. In the percent calculation that you did to compare to Paragraph 4, you would have only taken into account just the weights of CoQ<sub>10</sub> and limonene, wouldn't you?

A: In that – for that comparison with Figure 4, probably so.

(A-541.) Williams' prediction based on Figure 4 of the '786 patent does not take into account all the ingredients in the accused products, even though the patent, the file history and Williams himself all agreed that it was necessary to do so.

**C. The Williams May 4 And May 25 Declarations Were Late And Contained New Opinions.**

On May 4, 2012, the day the parties filed cross motions for summary judgment, JFI submitted a Declaration from Williams. In his May 4 Declaration, Williams changed his definition of melting point “to refer to the temperature at which the process of CoQ<sub>10</sub> crystal melting is observed.” (A-623 ¶ 26.) He also

provided the basis for the conclusory assertion in his February 10 Report that the amounts of ubiquinone and d-limonene were “within the eutectic range as described by the ‘786 patent.” (A-383 ¶ 26.) Williams explained in his May 4 Declaration that he used the lemon oil line in Figure 4 of the patent as a proxy for d-limonene and used that figure to predict whether certain binary mixtures of ubiquinone and d-limonene would exhibit a melting point reduction. (A-623-625 ¶¶ 27-28.)

On May 25, 2012, with its opposition to Soft Gel’s motion for summary judgment, JFI submitted another Declaration from Williams analyzing, for the first time, the Master Formulation Sheets, which identify the ingredients of the accused products and the manner in which they are mixed and processed. As of his April 11, 2012 deposition, Williams had not even seen these documents. (A-530-531.) Also for the first time, the May 25 Williams Declaration opined that the accused products were first prepared by making a binary mixture of ubiquinone and d-limonene, that other ingredients were added later. (A-1219-1220 ¶¶ 8-9.) Williams’ May 25 Declaration goes on to predict that these other ingredients would not impact that hypothesized melting point reduction. (A-1221-1223 ¶¶ 11-12.) At no time did Williams perform testing or assays that took into account all the ingredients of the accused products.

#### **IV. THE NAZZAL DECLARATION WAS LATE EXPERT TESTIMONY.**

Also on May 4, 2012, JFI submitted the declaration of its other retained expert witness, Nazzal. Nazzal discussed the alleged teaching of the ‘786 patent, just as any expert would. (A-709 ¶ 4 (“the ‘786 patent describes and teaches. . . .”); A-710 ¶ 7 (“The claims of the ‘786 Patent are directed to. . . .”); A-710 ¶ 9 (“The reduction in melting point. . . is demonstrated by Figs. 1-4 of the ‘786 patent.”).) The Nazzal Declaration mirrors the May 4 Williams’ Declaration’s discussion of Figure 4 of the ‘786 patent, and its use to predict whether certain binary combinations of ubiquinone and d-limonene would exhibit a melting point reduction. (Compare A-623-625 ¶ 27 with A-713-714 ¶ 14.)

#### **V. FACTS RELATING TO INEQUITABLE CONDUCT.**

The inequitable conduct claim is based on selective disclosures, misrepresentations and omissions in an unmistakably false declaration submitted to revive the ‘786 application after it was intentionally abandoned.

The ‘786 application was assigned to TTU and the TTU IP Office was involved in prosecuting it. (A-3049-3500.) K. Lance Anderson (“Anderson”) was the Interim Director and later Managing Director of the TTU IP Office during the relevant time period. (A-3046-3407.) Anderson was an attorney and a member of the patent bar. (A-3044-3045.) The TTU IP Office had outside counsel assist in prosecution of the ‘786 patent application. (A-3069-3070.) On or about

January 13, 2005, the Patent Office issued an office action regarding the '786 patent application. (A-2789-2887.) A response to the office action was due within three months, on April 13, 2005; that deadline, however, could be extended by an additional three months to July 13, 2005. (A-3132-3133.) TTU chose not to respond to the office action. (A-3132.) As a result, the Patent Office mailed a Notice of Abandonment regarding the '786 patent application on or about August 25, 2005. (A-2924-2925.)

On or about February 1, 2006, TTU filed a Petition to Revive the ‘786 patent application on the grounds that it was unintentionally abandoned (“the Petition”). (A-2966-2969.) The Petition was signed and filed by Mark Giarratana, who is also JFI’s counsel in this case. (A-2967.) In support of the Petition, Giarratana filed the Declaration of K. Lance Anderson (“the Anderson Declaration” or “the Declaration”). (A-2968-2969.)

Anderson swore in Paragraph 10 of his Declaration that “[a]s the six month deadline for responding to the outstanding office action approached, I had not received the required assistance from Dr. Khan, and therefore was unable to respond to the outstanding office action prior to the deadline.” (A-2969.) In fact, Anderson testified that TTU *could have* responded to the office action without Khan’s help. TTU’s counsel, Jennifer Yancy, actually proposed a response to the office action, in her January 21, 2005 letter reporting the office action to the client.

(A-2879-2880.) Anderson testified that TTU could have responded to the office action by authorizing its outside counsel, Jennifer Yancy, to respond as she had suggested in January 2005. (A-3256.) Anderson initially testified that TTU could have responded to the Office Action without Khan's help on JFI's direct examination:

Q: Could you respond to the Office Action without Dr. Khan's assistance before the thing -- before the deadline expired?

A: Well, you could have. One can respond to an Office Action if -- [interruption by JFI's counsel].

(A-3170; see also A-3171-3172) ("Q: Did you have any options available to you in the absence of Dr. Khan's assistance or communication? A: There's always options. . . .")

Anderson expanded on this testimony on cross-examination:

Q: And it was certainly possible for TTU to reach out to Sami Nazzal, Dr. Nazzal, to seek any help it needed in responding to the Office Action. Right?

A: There was -- we could have -- again, we could have done a lot of things at that point --

Q: And --

A: -- including authorizing Jennifer Yancy to respond as she suggested.

Q: And you also could have reached out to Dr. Khan for -- excuse me, Dr. Nazzal for any help you needed. Right?



A: We could have done that. We could have hired an independent consultant. And we could have also obtained an independent third party. We could have gone to colleagues within his former department. We could have, you know, done a lot of things like that.

Q: [TTU] could have done any number of those things --

A: Any number of things --

Q: -- in order to put in a response to the Office Action. Right?

A: Yes.

(A-3256-3257.)

Anderson testified that although TTU had many ways to respond to the office action without Khan's help, TTU made a business decision not to do so. TTU preferred to proceed with prosecution only in conjunction with a cooperative faculty inventor (Khan), as this maximized the chance of commercial success. Anderson explained that "continued alignment" with the faculty inventor "ensures the greatest likelihood of success," and is "a critical component to de-risking the opportunity," and is a "business consideration." (A-3255-3256.) For this reason, Anderson explained, TTU made a choice not to proceed in the absence of Khan's cooperation. (A-3254:10-A3256:3.) Another circumstance behind the decision not to respond was the absence of a commercial partner. (A-3256:7-9.) Anderson explained that TTU was not prepared to proceed with prosecution without Khan's cooperation, unless there was a commercial partner on the scene: "that was not

something we were going to do without it being a commercial partner.”  
(A-3261:15-20.)

Anderson stated in Paragraph 11 of his Declaration that “[w]ithin three months thereafter, [TTU] became aware of a party with expertise could assist in prosecution. . . .” (A-2969.) That party was JFI. (A-2053.) The Declaration, however, never reveals that the party “with expertise” was a newly arrived commercial partner that had purchased an option to buy the application if it could be revived. (A-3258-3259; A-2053-2054.) Under the agreement, JFI paid TTU \$13,000 to buy the option, which could only be exercised with an additional payment of \$12,000. (A-2933-2934; A-2054.)

## SUMMARY OF ARGUMENT

The District Court correctly granted summary judgment of noninfringement. JFI produced no admissible evidence that the accused products met the District Court's unchallenged construction of the melting point reduction limitation. Moreover, even though the patent, file history and Williams all agreed that one must test all of the ingredients of a composition to determine whether it results in a melting point reduction, JFI put forward no evidence of such testing.

The District Court did not abuse its discretion in excluding the untimely expert declarations of Williams and Nazzal.

The District Court erred as a matter of law in not giving the term “eutectic-based” its ordinary meaning.

The District Court abused its discretion in finding no inequitable conduct. In particular, the District Court erred as a matter of law in applying an overly restrictive test for deceptive intent. The District Court erred as a matter of law in applying a standard that required it to credit an unsupported “alternative inference.” The District Court erred as a matter of law in applying a standard that did not require it to assess the relative strength of the competing “alternative inferences” to determine the single most reasonable inference. The District Court’s finding that there was an alternative reasonable inference was clearly erroneous.

### **ARGUMENT AS APPELLEE**

#### **I. THE DISTRICT COURT CORRECTLY GRANTED SUMMARY JUDGMENT OF NONINFRINGEMENT.**

The District Court correctly granted summary judgment of noninfringement because JFI failed to carry its burden of coming forward with admissible evidence to create a genuine issue of material fact that the accused products met every limitation of the asserted claims.

Summary judgment of noninfringement is subject to de novo review. See Ormco Corp. v. Align Tech., Inc., 498 F.3d 1307, 1312 (Fed. Cir. 2007) (reviewing grant of summary judgment of noninfringement by determining “whether there

was no genuine issue of material fact.”). “[S]ummary judgment of noninfringement is . . . appropriate where the patent owner’s proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial.” TechSearch, L.L.C. v. Intel Corp., 286 F.3d 1360, 1369 (Fed. Cir. 2002).

**A. JFI’s Theory Of Infringement On Appeal Is The Theory That The District Court Excluded As Untimely Disclosed.**

JFI’s theory of infringement on appeal – based on analysis of Master Formulation Sheets, the assertion that a binary mix of ubiquinone and d-limonene is made before other ingredients are added, and comparisons to Figure 4 of the ‘786 patent – is precisely the theory that the District Court excluded as untimely disclosed.

Williams addressed the Master Formulation Sheets for the first time in his excluded May 25 Declaration. He purported to analyze the relative proportion of ubiquinone and d-limonene in the accused products. (A-1220 ¶ 9.) He also considered the order in which ingredients were mixed and processed. (*Id.*) He then purported to use Figure 4 of the ‘786 patent, to predict whether a binary mix of ubiquinone and d-limonene would result in a melting point reduction. (A-1220-1221 ¶¶ 9- 10.) He then relied on Soft Gel marketing brochures to opine that the composition remained liquid after the addition of further ingredients. (A-1223-1224 ¶ 14.) In particular, the “binary mixture” argument was raised for the first

time in Williams' May 25 Declaration. (A-1223-1224 ¶¶ 8-9.) Prior to that time, he had not even looked at documents listing all the ingredients of the accused products and the manner in which they were prepared. (A-530.)

The excluded "binary mixture" analysis is the theory of infringement set forth at pages 7 to 21 and 29 to 31 of JFI's opening appellate brief. For example, JFI states that the addition of other ingredients into the binary mixture "does not cause ubiquinone to transition from liquid to solid," pointing to the fact that the accused products are liquid at room temperature, and citing Williams' deposition testimony and his February 10 Report. (JFI Br. at 34.) Williams' February 10 Report provides no support for this argument, because as of February 10, Williams had not even looked at documents listing all the ingredients in the accused products, or the order or the manner in which they were mixed together or processed. (A-530-531.) Neither does the cited passage from the Williams deposition. In that testimony, Williams explains that his opinion on infringement is based on the claim construction that was rejected by the District Court: "this point is about it being dissolved." (A-537.) JFI is asserting an excluded theory of infringement, which is devoid of evidentiary support.

The District Court excluded this theory of infringement, and JFI cannot rely upon it on appeal. To the extent this Court reverses the exclusion of the untimely expert declarations, it should remand for further proceedings.

**B. JFI Offered No Admissible Evidence That The Accused Products Met The District Court's Unchallenged Construction Of The Melting Point Reduction Limitation.**

The Williams Reports of February 10, February 17 and March 15 were based on an improper claim construction – that “melt” was used interchangeably with “dissolve.” (A-380-381, A-434, A-465-466.) As of May 4, 2012, when cross motions were filed, JFI had offered no evidence that the accused products met the melting point reduction limitation properly construed.

Summary judgment is proper where there is no evidence that the accused products meet limitations of the claim properly construed. See Texas Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1565 (Fed. Cir. 1996) (expert testimony based on improper and rejected claim construction could not support infringement claim).

JFI incorrectly points to Williams’ testimony admitting the ordinary meaning of melting point, and suggests that this was the claim construction that Williams used in his opinions. (JFI Br. at 37.) Williams made clear, however, that his opinions were based on something other than the ordinary meaning of melting point: “to one of skill in this context,” i.e., the context of the ‘786 patent, “‘melt’ is used interchangeably with ‘dissolve’ or ‘solubilize.’” (A-489.) The District Court correctly noted that when pressed to explain how he could “predict” a melting point reduction, when he agreed with the patent and file history that such

reactions could not be predicted, Williams explained that infringement analysis was based on a theory that melt means dissolve: “I mean, this point is about it being dissolved. \* \* \* I’m putting together the different pieces saying that basically at – at room temperature this formulation exists as a solution.” (A-537.)

Ultimately, JFI argued that “melting point” properly construed is the temperature at which CoQ<sub>10</sub> is liquid in volatile essential oil. (A-16.) At no point did JFI offer evidence addressing whether the accused products met the District Court’s unchallenged construction of the melting point reduction limitation.

Because JFI’s opinions and evidence were based on an incorrect claim construction that effectively read the melting point reduction limitation out of the claims, the District Court properly granted summary judgment of noninfringement. Texas Instruments, 90 F.3d at 1565.

**C. JFI Offered No Evidence Of Chemical Testing Or Assays That Took Into Account All The Ingredients Of The Accused Products.**

Even though the patent, the file history, and Williams all agreed that melting point reductions could not be predicted and needed to be established by chemical testing and assays which took into account all the ingredients of the accused products, JFI offered no evidence of such testing or assays. Even to this day, JFI has no evidence of any testing that takes into account all the ingredients of the accused products.

JFI's argument that "the '786 patent rendered predictable that which was previously unpredictable" (JFI Br. at 36), is not only inaccurate, but it is the exact opposite of what the applicant told the Patent Office. During prosecution, the applicant sought to overcome prior art rejections arguing that eutectic effects cannot be predicted *a priori* and must, instead, be determined empirically by mixing two or more ingredients and assaying for reduction in melting point, concluding: "Therefore, as would be understood by a person of skill in the art *in view of the present teachings*, the eutectic effect does not necessarily and inevitably occur merely from the presence of the two ingredients (i.e., an essential oil and ubiquinone) in a mixture. *More importantly the eutectic effect does not occur merely because CoQ<sub>10</sub> and an essential oil are present at equal amounts in a mixture.*" (A-1899) (emphasis added.) This statement makes clear that melting point reductions are unpredictable even in view of the '786 patent's teachings. Similarly, the applicant sought to overcome prior art rejections arguing: "Significantly, the eutectic effect does not necessarily occur merely because CoQ<sub>10</sub> and an essential oil are present at equal amount in a mixture. *As taught in the present specification*, a eutectic composition is dependent on the relative proportions of all ingredients in the mixture." (A-1907 (bold italics added; underscore in original).) This statement makes clear that the '786 specification



itself teaches that eutectics and melting point reductions are unpredictable even in light of the claimed invention.

Williams agreed that “the eutectic effect does not necessarily and inevitably occur merely from the presence of two ingredients,” such as “essential oil and ubiquinone in a mixture.” (A-539.) Williams admitted that “the eutectic effect does not necessarily occur merely because CoQ<sub>10</sub> and essential oils are present in equal amounts in a mixture.” (*Id.*) Williams agreed that “a eutectic composition is dependent on the relative proportions of all ingredients in the mixture.” (A-539-540.) Williams’ agreement on all these points was not limited to the time before the inventors made their alleged discovery.

Given that the applicant told the Patent Office that eutectics and melting point reductions were unpredictable “in view of the present teachings” (A-1899) and “[a]s taught in the present specification” (A-1907), JFI’s current and contrary position that the ‘786 patent rendered “predictable that which was previously unpredictable,” is untenable. The applicant clearly represented to the Patent Office that eutectics and melting point reductions depended on the relative proportion of all ingredients in the mixture, and must be determined empirically by mixing the ingredients and assaying for a reduction in melting point.

JFI failed to create a genuine issue of material fact because it failed to perform the empirical testing, taking into account all the ingredients of the accused

products, which the specification, file history and Williams all agreed was required to determine whether the accused products met the melting point reduction limitation. Williams' admissible opinions on infringement were unsupported, conclusory, and insufficient to avoid summary judgment. Sitrick v. Dreamworks LLC, 516 F.3d 993, 1001 (Fed. Cir. 2008).

**D. Soft Gel's Marketing Materials Are Not Evidence Of Infringement.**

Soft Gel's promotional materials describing Soft Gel's products as crystal-free, solubilized or liquid do not create a fact issue precluding summary judgment. JFI got a patent on a eutectic-based delivery system which requires a reduction in the melting point of ubiquinone. JFI did not get a patent covering all compositions of ubiquinone that are crystal-free, solubilized or liquid. JFI is essentially looking at Soft Gel's end product, and assuming, without any basis, that the only way to get to that end product is through a melting point reduction. Williams never opined that melting point reduction is the only way to achieve a crystal-free, solubilized or liquid ubiquinone composition. To the contrary, Williams testified that ubiquinone would actually dissolve in essential oil, not melt. (A-491-492.) In fact, Soft Gel discovered that ubiquinone could be dissolved in d-limonene. The Patent Office awarded Soft Gel a patent on this invention. (A-410-423.) That patent was awarded to Soft Gel over and above the '786 patent. (Id.) (listing '786 patent as a cited reference.) Reducing the melting point of ubiquinone

and dissolving ubiquinone are two different things, as both experts agreed. (A-491-492; A-355 ¶¶ 45, 46.) In arguing for patentability, the '786 applicant argued that "[a]s is widely known by those of skill in the art, CoQ<sub>10</sub> is extremely insoluble even in organic solvents that dissolve most quinones." (A-1823.) Melting point reduction was presented as the alternative to dissolving. (A-62, A-64 '786 patent, 1:46-62, 2:32-35, 6:57-60.)

**E. There Is No Testing To Show That The Accused Products "Re-Dissolve," Which Williams Testified Was Necessary To Determine Whether The Accused Products Met The Claim Limitations.**

In his deposition, Williams testified that to determine whether a composition meets the claim limitations, one would need to expose it to temperatures lower than 25° C to see if the ubiquinone precipitates, and then expose it to a temperature of 37° C to see if it would "re-dissolve." (A-518:7-A-520:1; A-521:2-A-522:13.) Yet, Williams did not perform or rely on any such testing of the accused products. This further establishes that there was no evidence to create a fact issue on infringement, and that the District Court correctly granted summary judgment of noninfringement.

**II. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN EXCLUDING JFI'S UNTIMELY EXPERT DECLARATIONS.**

Under the District Court's scheduling order, all expert disclosures were due by February 17, 2012. (ECF No. 43.) JFI ignored this deadline and filed three untimely expert declarations: two which were filed with JFI's opening summary

judgment brief on May 4 and a third three weeks later on May 25. (A-614-644; A-706-717; A-1215-1228.) The issues addressed by the untimely expert declarations had been well-known since the beginning of the case. For example, in June 2011, Soft Gel provided an interrogatory response noting that JFI “has provided no evidence that Soft Gel’s accused products are a eutectic-based delivery system, that d-limonene melts or lowers the melting point of CoQ<sub>10</sub>, or that d-limonene and CoQ<sub>10</sub> form a eutectic mixture or a eutectic reaction. . . .” (A-480.)

Because JFI could offer no excuse for these delayed reports – the District Court rightly described JFI’s conduct as the “very definition of sandbagging” – the reports were excluded. (A-29.) JFI appeals the decision to exclude these reports, but a review of these reports and applicable law makes clear that the District Court made the right decision, a far cry from the “abuse of discretion” that JFI needs to prove in order to prevail on appeal.

As an initial matter, however, because JFI concedes that the exclusion of these untimely expert declarations did not deprive it of evidence necessary to raise a genuine issue of material fact on summary judgment, any error in exclusion of those Declarations would be harmless error.

**A. The Exclusion Of Admittedly Cumulative Testimony Would Be Harmless Error.**

JFI concedes that the exclusion of the Williams and Nazzal Declarations did not deprive it of evidence necessary to create a genuine issue of material fact on

summary judgment. (See JFI Br. at 52, 62 (acknowledging that exclusion of Williams and Nazzal Declarations “may not have deprived [JFI] of evidence creating a genuine issue of material fact for trial.”).) JFI’s concession is unavoidable given its contention that the excluded declarations contained no opinions not already contained in Williams’ prior expert reports. Because JFI does not, and cannot, contend that the exclusion of the Williams and Nazzal Declarations was prejudicial, any error in their exclusion would be harmless error. Molina v. Asture, 674 F.3d 1104, 1119 (9th Cir. 2012), citing, Shinseki v. Sanders, 556 U.S. 396, 406 (2009).

**B. The District Court Has “Particularly Wide Latitude” To Determine Whether An Untimely Expert Disclosure Should Be Excluded.**

Untimely expert reports should be excluded unless the failure to timely disclose information is harmless or substantially justified. Fed. R. Civ. P. 37(c)(1); Yeti By Molly Ltd. v. Deckers Outdoor Corp., 259 F.3d 1101, 1106 (9th Cir. 2001). Unless the party proffering the late disclosed expert evidence can show that the violation is substantially justified or harmless, exclusion is automatic and mandatory. Plumley v. Mockett, 836 F. Supp. 2d 1053, 1065-66 (C.D. Cal. 2010); Quevedo v. Trans-Pac. Shipping, Inc., 143 F.3d 1255, 1258 (9th Cir. 1998) (untimely expert report properly stricken where party offering it had not sought

extension and failed to justify untimely production). The party facing exclusion has the burden of demonstrating substantial justification or harmlessness. Id.

This Court adopts the regional circuit’s standard of review when a party challenges the decision to exclude evidence. Tokai Corp. v. Easton Enters., Inc., 632 F.3d 1358, 1364 (Fed. Cir. 2011). The Ninth Circuit, which is the applicable circuit here, uses the “abuse of discretion” standard. Id. at 1364; Payne v. Exxon Corp., 121 F.3d 503, 507 (9th Cir. 1997). In addition, the Ninth Circuit has made clear that it gives a decision to exclude untimely expert reports even more deference than it typically gives under the abuse of discretion standard. Yeti by Molly, 259 F.3d at 1106 (upholding a district court’s decision to exclude an untimely expert report while stating that “although we review every discovery sanction for an abuse of discretion, we give particularly wide latitude to the district court’s discretion to issue sanctions under Rule 37(c)(1)”).

**C. The May 4 And May 25 Declarations Of Williams Were Properly Excluded Because They Add New Information, Were Filed Three Months Late, And JFI Has Not Provided Any Justification For Their Late Disclosure.**

JFI does not dispute that the two Williams' Declarations were filed months after rebuttal expert reports were due and has never argued that its delay was justified. Rather, it now argues on appeal that the declarations are not new expert reports because they do not contain any new opinions. (See Jarrow Br. at 43-51.) This claim is demonstrably false.

As the District Court properly concluded, the May 4 declaration “shifted Dr. Williams’ definition of ‘melting point’” and “provided a much deeper analysis . . . in light of this new construction.” (A-28.) Williams went from a passing, one sentence reference to “eutectic range” in his February 10 Report to a detailed analysis in his May 4 Declaration using Figure 4 to predict whether various binary combinations would result in a melting point reduction. (Compare A-383 at ¶ 26 with A-623-625.)

The centerpiece of the May 25 Williams Declaration is an analysis of Soft Gel’s Master Formulation Sheets, which Williams had not previously reviewed. (A-530-531.) The District Court accurately described the new opinions found in the May 25 Declaration:

The May 25 Declaration goes even further, relying on documents Dr. Williams admitted he had not reviewed as late as his deposition and for the first time purporting to predict the eutectic nature of the Accused Supplements in light of all their ingredients. *See Williams May 25 Decl.* ¶ 8. The May 25 Declaration also opines on a new theory of infringement whereby each of the Accused Supplements is purportedly produced by first creating a binary mixture of CoQ<sub>10</sub> and d-limonene, allowing Dr. Williams to conclude that the melting point of the CoQ<sub>10</sub> has been reduced based on FIG. 4, and to which the other ingredients are then added. *Id.* ¶ 10. He then dedicates several pages to previously undisclosed opinions regarding why the addition of these ingredients does not affect the eutectic nature of the Accused Supplements. *Id.* ¶¶ 11-13.

(A-28.)

Simply put, the May 4 and May 25 Declarations contain new, previously undisclosed opinions. And because it is undisputed that these disclosures were late without any justification, the District Court did not abuse its discretion in striking them. Under JFI’s apparent theory, an expert can simply opine “infringement” and subsequently follow up with an endless series of “expansions” and “supplements.” This is not correct. The District Court has broad discretion to enforce its expert disclosure deadlines and exclude untimely disclosures. Yeti by Molly, 259 F.3d at 1106.

The cases cited by JFI do nothing to change this.

Thompson v. Doane Pet Care Co., 470 F.3d 1201 (6th Cir. 2006), does nothing more than rebuke a district court judge who held that an expert, during direct examination, could only “read the report [to the jury] and not one word more.” Id. at 1202; see also Lab. Skin Care, Inc. v. Ltd. Brands, Inc., C.A. No. 06-601-LPS, 2011 WL 4005444 (D. Del. Sept. 8, 2011) (holding that experts may “elaborate” on the opinions in their expert reports at trial, but stating nothing to support the proposition that an expert can submit untimely expert reports or change their opinions), aff’d, F. App’x 672 (Fed. Cir. Sept. 10, 2012). The District Court’s decision here is a far cry from this cramped view of expert reports. Soft Gel has never contended that Williams must simply read his expert reports to the jury. Rather, Soft Gel and the District Court have objected to Williams’ untimely



reports that presented new opinions. The Thompson, Lab. Skin Care, Dow, and Forest Labs cases cited by JFI do not even address this issue and accordingly are inapplicable to this appeal.

Similarly, McHugh v. Olympia Entm't, Inc., 37 F. App'x 730 (6th Cir. 2002), Volterra Semiconductor Corp. v. Primarion, Inc., 796 F. Supp. 2d 1025 (N.D. Cal. 2011), Hochstein v. Microsoft Corp., No. 04-cv-73071, 2006 U.S. Dist. LEXIS 74574 (E.D. Mich. Oct. 13, 2006), and Hill v. Reederei F. Laiesz G.M.B.H., Rostock, 435 F.3d 404 (3d Cir. 2006), all stand for the proposition that experts may rebut opinions presented by other experts. Once again, neither Soft Gel nor the District Court has sought to prohibit Williams from presenting proper rebuttal testimony – in fact, the District Court contemplated rebuttal testimony from experts when it ordered that rebuttal expert reports were due on February 17. However, by waiting three months after this deadline and a month after the close of expert discovery to file the reports at issue, JFI's submissions are not the type of proper rebuttal addressed in the cases above, but instead constitute improper sandbagging. (A-29.)

**D. The Nazzal Declaration Was Properly Excluded Because It Contained Expert Opinion Testimony, Was Filed Three Months Late, And JFI Has Not Provided Any Justification For Its Late Disclosure.**

Much like with the Williams Declarations, JFI does not dispute that the Nazzal Declaration was filed late nor does it argue that this tardiness was justified.

Instead, it argues that Nazzal did not provide expert testimony, thus his report was not subject to the expert disclosure deadlines. Again, JFI has incorrectly described the relevant portions of Nazzal's Declaration.

The key distinction here is between expert and lay testimony, not expert and lay witnesses. (A-29 (citing Eugene Baratto & Textures, LLC v. Brushstrokes Fine Art, Inc., 701 F. Supp. 2d 1068, 1074 (W.D. Wis. 2010).) If the testimony at issue “could have been offered by any individual with specialized knowledge of the [relevant topic,]” then it is expert testimony. See Baratto, 701 F. Supp. 2d at 1074 (citing WNS Holdings, LLC v. United Parcel Serv. Inc., 2009 WL 2136961 at \*2 (W.D. Wis. July 14, 2009), aff’d, 368 Fed. App’x 85 (Fed. Cir. 2010).) Here, the relevant portions of Nazzal’s declaration could have been provided by any expert in the field, which is particularly evident because Nazzal’s opinions actually mirror the opinions of Williams:

The portions of Dr. Nazzal's [D]eclaration pertinent to Plaintiff's infringement contentions are expert opinions that could have been provided by anyone of skill in the art. They are not based on Dr. Nazzal's first-hand experiences conducting the background experiments, for example. Rather, they are largely duplicative of and track Dr. Williams' reports. *See Nazzal Decl.*, ¶ 14 ("lemon oil, which is reported to be 90% d-limonene, reduces the melting temperature of CoQ<sub>10</sub> to below about 37 C at a "C:L" ratio (i.e., CoQ<sub>10</sub>:Lemon oil) of 60:40. Because lemon oil is 90% d-limonene, the observed depression in CoQ<sub>10</sub>'s melting temperature can be attributed to d-limonene"); ¶ 15 ("The '786 patent describes and teaches that mixing CoQ<sub>10</sub> with a suitable amount of a volatile essential oil would melt the CoQ<sub>10</sub> according to FIG. 4, which could then be mixed with additional ingredients using routine experimentation and optimization such that

the solubility of the CoQ<sub>10</sub> in the entire multi-component system can be maintained at a desired temperature.”).

(A-29.)

Because the Nazzal Declaration presents expert opinion, its disclosure on May 4 was undoubtedly late and the District Court properly excluded it. The cases cited by JFI all stand for the proposition that an inventor can testify regarding his personal experience with the invention. (JFI Br. at 54-55.) As the District Court noted, “JFI’s recitation of the law is correct insofar as it goes, but it does not end the inquiry.” (A-29 Decision at 22.) The important question is whether the testimony at issue is expert testimony. Here, the relevant portions of Nazzal’s Declaration are expert testimony; and thus, were correctly stricken as untimely.

## ARGUMENT AS CROSS APPELLANT

**I. THE DISTRICT COURT ERRED IN NOT GIVING “EUTECTIC-BASED” ITS ORDINARY MEANING.**

The District Court erred in not giving “eutectic-based” its ordinary meaning. The Federal Circuit reviews claim construction de novo. Lighting Ballast Control LLC v. Philips Elec. North Am. Corp., No. 2012-1014, \_\_ F.3d \_\_, 2014 WL 667499, \*1 (Fed. Cir. Feb. 21, 2014) (en banc). Because JFI had no evidence that the accused products met the ordinary meaning of “eutectic-based,” this is, at a minimum, an alternative basis for affirming the judgment of noninfringement.

In the District Court, Soft Gel contended that “eutectic-based” in the preamble was limiting and should be given its ordinary meaning. (A-1293-1296,

see A-997-999.) The District Court correctly noted that the ordinary meaning of eutectic was undisputed: “a *mixture* that must demonstrate a melting point that is lower than the melting point of its component ingredients.” (A-14 (emphasis in original).) The District Court went on to state that whether the preamble is limiting “hinges on whether the term ‘eutectic’ is given its ordinary meaning.” (Id.) The District Court declined to give the term its undisputed ordinary meaning and concluded that “‘eutectic’ and ‘eutectic-based’ more broadly describe mixtures in which only the melting point of one ingredient – ubiquinone – had been reduced.” (A-15.) The District Court went on to hold that the eutectic language in the preamble was “merely duplicative” of the melting point reduction limitation of the claims. (Id.) In this regard, the District Court erred in two respects: not giving the term its ordinary meaning and in not holding that the preamble was limiting.

It is a bedrock principle of patent law that the claims define the invention and the scope of the patentee's right to exclude. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). Claim terms are generally given their ordinary and customary meaning to one of skill in the art. Id. at 1312. The claims must be read in light of the specification and prosecution history. Id. at 1315. There are only two exceptions to the general rule that claim terms are given their ordinary and customary meaning: 1) where the patentee acts as his own

lexicographer and clearly sets forth a different definition for the term; and 2) where the patentee disavows the full scope of the term. Id. at 1316.

**A. All Claims Require A Eutectic-Based Delivery System.**

The ‘786 patent has three independent claims, claims 1, 4 and 10. Claims 1 and 10 expressly recite a “eutectic-based delivery system.” While Claim 4 does not expressly recite a “eutectic-based delivery system,” each claim that depends from claim 4, recites “[t]he eutectic-based delivery system of claim 4.” (See A-71 ‘786 patent, claims 5-7.) During prosecution, the applicant deleted the words “eutectic-based” from application claim 6 (which became claim 4 of the patent), but made clear that all claims require a eutectic-based delivery system. (See A-1832, A-1836.) Thus, all claims of the ‘786 patent require “a eutectic-based delivery system.”

**B. Eutectic Should Be Given Its Undisputed Ordinary Meaning.**

“Eutectic” is a technical term that is well-understood in the field. Williams agreed that the ordinary meaning of eutectic is directed to a composition that melts at a lower temperature than its ingredients. (A-380 ¶ 19 (“Generally, a eutectic mixture is formed where a mixture of two ingredients demonstrates a lower melting point than either of the two ingredients alone.”)); Phillips, 415 F.3d at 1317-18 (proper to consider expert testimony on meaning of technical term).

The District Court, however, did not give eutectic its ordinary meaning, reasoning that to do so would exclude certain embodiments, and in this the District Court erred. (A-14-16.) The case law addressing claim construction that excludes disclosed embodiments, involves situations in which a claim term “has multiple ordinary meanings,” some of which include and others exclude certain embodiments. Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1383 (Fed. Cir. 2008). That is not the present situation, because there are not multiple ordinary meanings of “eutectic.” A court cannot re-write the claims to encompass embodiments disclosed in the specification. Chef Am., Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1372, 1374 (Fed. Cir. 2004) (refusing to re-write claims, even though claims as written would exclude both disclosed working embodiments). There is no indication that the inventor acted as his own lexicographer and clearly adopted a special definition for this well-understood technical term. See Thorne, 669 F.3d at 1365. Nor is there any indication that the inventor disclaimed certain claim scope. Id.

For these reasons, the District Court’s reliance on Verizon Servs. Corp. v. Vonage Holdings Corp., 503 F.3d 1295 (Fed. Cir. 2007) is misplaced. In Verizon, this Court found no error in the district court’s rejection of Vonage’s proposed construction of the term “destination” in the phrase “destination address” to refer only to a final destination as set forth in the specification. *Id.* at 1304. “[T]he

ordinary meaning of the term ‘destination’ [in Webster’s Dictionary] is not limited to a final destination.” *Id.* at 1308. Further, there were multiple meanings for “destination address” including both a “‘public packet data network,’ i.e., the internet,” and “a telephone number” as disclosed in the specification. *Id.* at 1305.

In contrast, in the instant matter, “eutectic” does not have multiple ordinary meanings. *See Flexsys Am. L.P. v. Kumho Tire U.S.A., Inc.*, 695 F. Supp. 2d 609, 620 (N.D. Ohio 2010) (distinguishing *Verizon* and finding multiple uses of the word “destination”). Also, as discussed below, the applicant repeatedly used the ordinary meaning of eutectic-based to distinguish the prior art, which supports giving that term its ordinary meaning.

### **C. The Preamble Is Limiting.**

#### **1. The Applicant Used The Preamble To Distinguish Prior Art.**

Where, as here, the preamble is used to distinguish prior art during patent prosecution, the preamble serves as a claim limitation. *Invitrogen Corp. v. Biocrest Mfg., LP*, 327 F.3d 1364, 1370 (Fed. Cir. 2003) (holding that the term in the preamble served as a claim limitation because the inventor used it to distinguish the prior art); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1347-48 (Fed. Cir. 2002) (same); *Applied Materials Inc. v. Advanced Semiconductors Materials Am., Inc.*, 98 F.3d 1563, 1572-73 (Fed. Cir. 1996) (“Whether a preamble stating the purpose of the invention constitutes a limitation of the claimed process

determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history.”).

During prosecution, the applicant used the ordinary meaning of “eutectic-based” to distinguish the prior art. For example, the applicant distinguished the Shapira prior art, arguing that: “Shapira does not teach, suggest or enable an orally administered dietary supplement composition including a eutectic-based delivery system comprising ubiquinone . . . .”; “there is nothing in Shapira . . . that would have led the artisan to create a eutectic mixture of ubiquinone and a volatile oil”; and because “the instantly claimed eutectic mixture was . . . unpredictable, the present rejection should be withdrawn . . . .” (A-1840-1841.) In distinguishing this prior art the applicant did not assert that “eutectic” or “eutectic-based” was merely a “convenient label” for melting point reduction or other claim limitations, as it argued in the District Court. (A-994.) Rather the preamble was expressly used to distinguish the prior art, establishing that it is a limitation of the claims.

The applicant also argued that the Shuch prior art “is insufficient to result in an eutectic effect” and that “[t]herefore, [Shuch] does not teach or enable a dietary supplement composition *including a eutectic-based delivery system*, comprising ubiquinone and a sufficient amount of volatile oil or volatile ingredient of an essential oil to solubilize ubiquinone and reduce the melting point of ubiquinone to



37[°] C or below, as claimed.” (A-1907 (emphasis added).) The applicant concluded “[b]ecause Shuch fails to teach every element as recited in the claim,” it fails to anticipate. (A-1908. See also A-1822-1824; A-1899-1900; A-1904-1906; A-1908; A-1910-1911; A-1869.) Further, when the claims were amended to include the term “eutectic-based,” the applicant stated that “support for this amended [sic] is found in Paragraph [0009] where it is disclosed that the self-nanoemulsified drug delivery system is eutectic based.” (A-1955.) If the term were not a claim limitation it would not need support.

Moreover, the patent makes clear that “eutectic-based” is a claim limitation, emphasizing the term in the patent’s title, the summary of invention and detailed description of invention sections, and referencing “eutectic” more than twenty times. Invitrogen, 327 F.3d at 1370; Cruciferous Sprout, 301 F.3d at 1347-48.

## **2. The Preamble Provides Antecedent Basis.**

The preamble is limiting when, as here, limitations in the body of the claim rely upon and derive antecedent basis from the preamble. Eaton Corp. v. Rockwell Int’l Corp., 323 F.3d 1332, 1349 (Fed. Cir. 2003); Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1997). The body of asserted claims 1, 2, 8, 10, 12 and 13 refer to “the orally administered dietary supplement.” (A-71.) The antecedent basis for that limitation is the dietary supplement recited in the preamble, which specifically includes a “eutectic-based delivery system.” Thus, the body of these claims is

“referring back to the particular [dietary supplement] . . . previously described in the preamble.” (Id.) Similarly, the bodies of asserted claims 5, 6 and 9 refer back to the “eutectic-based delivery system of claim 4.” (Id.) Claim 4 should be construed to require a eutectic-based delivery system because the applicant stated in the file history that all claims require one, (A-1836), and claims 5, 6 and 9 expressly refer to the eutectic-based delivery system of claim 4. (A-71.)

### 3. JFI And Williams Treated The Preamble As Limiting.

In addition, JFI and Williams treated the preamble as a claim limitation. For example, in his infringement claim chart, Williams referred to “[t]he ‘eutectic-based delivery system’ limitation.” (A-401.) Williams also emphasized the significance of the eutectic-based system to the patent claims in his report on invalidity. (A-433-435.)

Throughout this case, JFI has taken the position that the “eutectic-based” requirement in the preamble is a claim limitation. In other words, to be covered by the claims, an accused product must be “eutectic-based.” Williams explicitly took this position in his February 10 Report on infringement. (A-383 ¶ 27 (“in my opinion the Accused SGTI Products . . . are a ‘eutectic-based delivery system’ as described **and claimed** by the ‘786 patent”) (emphasis added).) He also treated the preamble as limiting in his February 17 Report on invalidity, when he used the “eutectic-based” limitation to distinguish the prior art. (A-437 ¶ 25 (“JP ‘616

[Motoyama] cannot be said to have described or enabled the claimed eutectic-based delivery system.”.) (See also A-439 ¶ 29 (asserting that prior art does not disclose a eutectic mixture).) Williams reiterated this position in his March 15 Report, referring a “eutectic mixture or eutectic-based system, as described **and claimed** by the ‘786 patent.” (A-462: ¶ 18 (emphasis added).) On summary judgment, JFI also relied on limitations in the preamble to distinguish the Anderson prior art. (A-1166.)

## **II. THE DISTRICT COURT ABUSED ITS DISCRETION IN FINDING NO INEQUITABLE CONDUCT.**

The District Court abused its discretion in finding that there was no specific intent to deceive and therefore no inequitable conduct. Allen Eng. Corp. v. Bartell Indus., 299 F.3d 1336, 1351-52 (Fed. Cir. 2002). “An abuse of discretion occurs when (1) the court’s decision is clearly unreasonable, arbitrary, or fanciful, (2) the court’s decision is based on an erroneous construction of the law, (3) the court’s factual findings are clearly erroneous, or (4) the record contains no evidence upon which the court rationally could have based its decision.” Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223, 1229 (Fed. Cir. 2007). “If the district court’s determination of inequitable conduct is based on a clearly erroneous finding of materiality and/or intent, it constitutes an abuse of discretion.” Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008). Here, the

District Court's finding of fact that there were reasonable alternative inferences regarding patentee's intent was clearly erroneous.

To prove inequitable conduct, the challenger must show by clear and convincing evidence that the patent applicant (1) made an unmistakably false declaration or a misrepresentation or omission that is but-for material; and (2) had specific intent to deceive. See Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1290-93 (Fed. Cir. 2011) (en banc). Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence.” Id. at 1290. “[S]pecific intent to deceive ‘must be the single most reasonable inference to be drawn from the evidence.’” Id.

In this case, crediting Anderson's testimony, TTU was able to respond to the office action but chose not to. The applicant made that choice for business reasons – the lack of inventor cooperation and the lack of any prospect of commercial success. After TTU let the application go abandoned, a commercial partner (JFI) appeared. TTU sought revival, asserting that it had been unable to respond to the office action without the inventor's help, and that a party with the necessary “expertise” had only just appeared. The applicant did not disclose that it could have responded without the inventor's help but chose not to. Nor did the applicant disclose that revival was motivated by arrival of a commercial partner. Nevertheless, the District Court found that there was an alternative reasonable

inference to explain the misrepresentations and omissions, and that therefore deceptive intent had not been proven. (A-47-48.)

**A. The District Court Erred As A Matter Of Law In Applying An Overly Restrictive Standard In Determining Deceptive Intent.**

The District Court erred as a matter of law in applying an overly restrictive standard in determining whether there was deceptive intent. The District Court’s decision below reflects that it incorrectly read Therasense as setting a practically insurmountable standard, where the court is obligated to credit alleged alternative inferences, despite their lack of evidentiary support. Further, the District Court erred in applying a standard that did not require it to assess the relative strength of the competing inferences to determine whether deceptive intent is the single most reasonable inference. Instead, the District Court applied a standard in which there can be no deceptive intent unless the evidence produces “a single reasonable inference.” (A-48.) In this, the District Court erred as a matter of law, and the judgment should be reversed and remanded for consideration under the proper standard.

The standard applied by the District Court improperly constrained a doctrine which “is not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion.” Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806, 814 (1945), quoting, Keystone Driller Co. v. General Excavator Co., 290 U.S. 240, 245-46 (1933). To

the extent the District Court’s decision represents a faithful application of Therasense, this Court should revisit Therasense to restore to the district courts the ability to decide inequitable conduct unrestricted by rigid formulas that trammel the free and just exercise of discretion. See General Electric Co. v. Mitsubishi Heavy Indus., Ltd., 946 F. Supp. 2d 582, 591 (N.D. Tex. 2013) (stating that Therasense sets a “nearly insurmountable standard” that has “severely limited the ability of district court judges to make inferences based on the evidence.”).

**1. The District Court Erred As A Matter Of Law In Applying A Standard That Required It To Credit An Unsupported Inference.**

The District Court erred in crediting an unsupported inference that Anderson could not (or believed he could not) respond to the office action without Khan’s assistance. In Therasense, this Court stated that specific intent to deceive must be the “single most reasonable inference.” 649 F.2d at 1290. But Therasense did not suggest that in assessing intent, all alleged alternative inferences must be accepted, even if they are not supported by evidence. It would be the rare case – perhaps one with a contemporaneous, videotaped confession – that some alternative inference could not be hypothesized: “He forgot,” “He was sloppy,” “He was mistaken.” In applying a standard that required it to credit an “alternative inference” – that TTU was unable to respond to the office action without Khan’s assistance – which was

unsupported and contrary to Anderson’s own testimony, as shown below, the District Court erred as a matter of law.

**2. The District Court Erred As A Matter Of Law In Applying A Standard That Did Not Require It To Assess The Strength Of The Competing Inferences.**

The District Court erred as a matter of law in applying a standard that did not require it to assess the relative strength of the competing inferences it posited. Even where an alternative inference has some evidentiary support that should not end the inquiry. Rather, the District Court should assess, at least to some degree, the relative strength of the competing inferences to determine whether deceptive intent is the single most reasonable inference. Therasense, 649 F.3d at 1290. Therasense limited, but preserved, the doctrine of inequitable conduct. On remand in Therasense itself, the district court found inequitable conduct despite testimony and arguments that there was no deceptive intent. 864 F. Supp. 2d 856, 868 (N.D. Cal. 2012) (reasoning that the explanation for the withholding simply lacked sufficient coherence and consistency compared with the rest of the record). Alternative inferences and explanations for nondisclosure were also assessed and rejected in Aventis Pharma S.A. v. Hospira, Inc., 675 F.3d 1324, 1335 (Fed. Cir. 2012). The District Court erred as a matter of law in not evaluating the strength of the competing inferences.

**B. The District Court's Conclusion That One Could Reasonably Infer That Anderson Believed That He Could Not Respond To The Outstanding Office Action Without Khan's Assistance Or Without Violating Some TTU Policy Is Clearly Erroneous.**

The District Court found that there was not clear and convincing evidence of specific intent to deceive, because there was an alternative reasonable inference: that Anderson thought he could not respond to the office action without Khan's help and without violating a policy of TTU requiring faculty participation. (A-48.) The District Court's underlying factual finding in this regard was clearly erroneous.

**1. Anderson Testified That TTU Could Have Responded To The Office Action Without Khan's Assistance.**

Anderson asserted in his Declaration that TTU was unable to respond to the office action without Khan's assistance. (A-2969 ¶10 ("I had not received the required assistance from Dr. Khan, and therefore was unable to respond to the outstanding office action prior to the deadline.").) The District Court concluded that one could reasonably infer that this statement was true and that therefore, there was an alternative reasonable inference precluding a finding of specific intent to deceive. (A-45-47.)

The District Court's finding is clearly erroneous because Anderson testified that there were many ways that TTU could respond to the office action even without Khan's assistance, including: 1) by authorizing its outside counsel,



Jennifer Yancy, to respond as she suggested; 2) by getting the assistance of co-inventor Nazzal; 3) by hiring an independent consultant; and 4) by seeking assistance from other faculty at TTU. (A-3256-3257 (stating, in part, that TTU “could have done” any number of those things to put in a response to the office action, “including authorizing Jennifer Yancy to respond as she suggested”).) This testimony establishes as fact that TTU was able to respond to the office action without Khan’s help.

The District Court found “there [wa]s evidence that [TTU] did not consider those options to be realistic by the summer of 2005, given that [TTU] had relied on Dr. Khan’s assistance throughout the patent prosecution.” (A-46.) This finding is clearly erroneous. Anderson testified that TTU “could have” responded to the office action in any number of ways. (A-3256-3257.) The most straightforward option open to TTU was to authorize Yancy to respond as she suggested in her January 21, 2005 letter reporting the office action. (A-2879-2880, Ex. 531.) Anderson’s own testimony (quoted above) and Exhibit 531 show that this option was available at the time and enabled TTU to respond to the office action without Khan’s help and avoid abandonment. That Yancy’s proposed response did not explicitly address the obviousness rejection is irrelevant because Anderson, who was himself a registered patent attorney (A-3045), clearly believed that he could have responded to the office action simply by giving Yancy a green light to

proceed as she suggested. (A-3256-3257.) Further, because the obviousness basis rejection applied to only 8 of the 20 pending claims, even without addressing it, TTU could have adequately responded with respect to 12 of the 20 pending claims, and filed a continuation to further prosecute additional claims.

Even if Anderson had some uncertainty about narrowing the claims, or the commercial potential of claims amended as Yancy suggested, that does not mean that TTU was unable to respond. Anderson's testimony proves that TTU was able to respond, even if it chose not to.

**2. There Is No Evidence To Support An Inference That Anderson Believed That Options For Responding Without Khan's Assistance Were No Longer Viable.**

The District Court's finding that by July 7, it was too late to pursue other options, or that they were no longer viable, is clearly erroneous. (See A-46.) The District Court cites JFI's post-trial brief at 5:10-19 for this proposition, (A-46 Order at 11), but none of JFI's citations to the record support this assertion. Anderson testified that even as late as June 30, and even right up to the deadline, there was still time to respond: "There was still time. This is a business of deadlines. You saw from previous Office Actions you sometimes get right down to the wire. There was still time." (A-3165.) Moreover, on July 8, Anderson wrote to Khan telling him to contact Yancy if he wanted to file a response (A-2923), demonstrating that even on that date it was not too late to respond.

(A-3226-3227.) Lastly, and most importantly, Anderson himself testified that TTU could have pursued these other options to put in a response to the office action. Anderson did not testify that it was too late, or impractical to have Jennifer Yancy respond as she suggested. He clearly testified that this was a viable option that was open to him. (A-3256-3257.)

**3. TTU Had No Policy Requiring Faculty Involvement, Only A Preference.**

The District Court's finding that one could reasonably infer that Anderson believed that it was not possible to respond to the office action without deviating from a TTU policy which requires that all patents be prosecuted with the assistance of the faculty inventor (A-48), is clearly erroneous. Anderson testified that TTU had no policy requiring faculty inventor participation; this was merely a preference. (A-3205.)

Anderson also testified as to the reason for this preference. The presence of the faculty inventor assured the best chance for a commercializing the invention. (A-3255-3256 (testifying that “continued alignment” with the faculty inventor “ensures the greatest likelihood of success,” and is “a critical component to de-risking the opportunity,” and is a “business consideration”).) Anderson explained that TTU would be happy to proceed without the cooperation of the faculty inventor, if there was a commercial partner in place. (A-3261 (proceeding without Khan’s cooperation “was not something we were going to do without it

being a commercial partner [in place]”).) Mark Giaratana testified to his recollection of a conversation in which Anderson explained that “he determined it wasn’t worth it, meaning it wasn’t worth filing the response” without the cooperation of the faculty inventor. (A-2076-2077.) To the extent Anderson did not want not to respond because he had neither the inventor’s cooperation nor a commercial partner, this was merely a business decision and a choice not to respond, not an “inability” to respond. Anderson testified that there was “no other option under the circumstances,” (A-3258), but those “circumstances” were merely TTU’s choice that it would not proceed without Khan’s cooperation or a commercial partner. (A-3255-3256; A-3261.) That TTU made a choice that it would respond only under optimal circumstances does not mean that TTU was unable to respond under sub-optimal circumstances. The District Court’s finding that this alternative scenario is reasonable and negates deceptive intent is clearly erroneous.

**C. The District Court’s Finding That Anderson Believed The Abandonment Was Unintentional Is Clearly Erroneous.**

To the extent the District Court found that Anderson believed that the abandonment was unintentional, that finding was clearly erroneous. Anderson testified that he did not know whether the delay was unintentional. (A-3241.)

**D. The District Court Erred As A Matter Of Law In Not Addressing The Motivation For Revival.**

The District Court failed to address Soft Gel's arguments that the applicant failed to disclose the motivation for the revival and that the Anderson Declaration was false because the party with expertise was actually a newly arrived commercial partner. (See A-3358.) These issues were fully developed and argued before the District Court. Accordingly, this Court has jurisdiction to review these arguments. See Eagle Comtronics v. Arrow Commc'n Labs., Inc., 305 F.3d 1303, 1316-1317 (Fed. Cir. 2002) (observing that it had jurisdiction to consider an alternative noninfringement argument that had been fully developed for summary judgment motion despite district court's failure to address argument or construe the claim terms).

The District Court erred as a matter of law in not addressing the motivation for revival. As noted above, Anderson, on behalf of TTU, made a business decision not to respond to the office action. Yet, his Declaration portrays this choice, as an "inability" to respond imposed on him by the lack of technical assistance from Khan.

The Declaration also states that within three months of abandonment, a party "with expertise" appeared on the scene to assist in prosecution. (A-2969 ¶ 11.) The Declaration never discloses, however, that the party with expertise was the commercial partner that had previously been missing. (Id.) Further, the

Declaration fails to state that the “party with expertise” was a commercial entity that paid for the right to have its lawyers petition to revive and for an option to buy the application for an additional payment, if the revival was successful. This omission continues the pattern of selective omission and disclosure by which the failure to respond was portrayed as an “inability to respond,” imposed by uncontrollable outside forces, rather than the calculated business decision that it was.

Anderson and Giarratana both knew about the commercial relationship between TTU and JFI as they negotiated the contract. (A-2932-2934.) Both knew that JFI was taking over prosecution with TTU acting as a mere figurehead until the revival could be accomplished. There is no evidence that Anderson reviewed or provided comment on the office action response that Giarratana submitted with the petition to revive. Nor is there any evidence that TTU would have pursued the prosecution without financial payment from JFI. To the contrary, the agreement between JFI and TTU specifies that JFI will pay for its lawyers to prepare and prosecute the petition to revive. (A-2933, ¶ 3.) Both Anderson and Giarratana knew that the revival was motivated by the arrival of a commercial partner. Both knew that these undisclosed facts were but-for material because they contradict the assertion in the Declaration that the revival was motivated by the discovery of a party with expertise. Both Anderson and Giarratana helped prepare the Anderson

Declaration and decided what should go into it and what should stay out of it. (A-3188; A-2032; A-2070; A-2091; A-2049-2051; A-3342.) As such, they both made a deliberate decision to omit the known facts. The District Court erred in not considering this evidence of deceptive intent.

**E. The District Court's Conclusion That There Was No Specific Intent To Deceive Was Not Proven Because There Was An Alternative Reasonable Inference Is An Abuse of Discretion.**

The District Court's conclusion that specific intent to deceive was not proven because there was an alternative reasonable inference is an abuse of discretion. The conclusion was based on an overly restrictive interpretation of the deceptive intent test of Therasense, and was based on clearly erroneous findings of fact, including the finding that the many ways TTU could have responded to the office action, even up to the last minute, somehow became unfeasible by the summer of 2005. The District Court's conclusion also failed to consider intent to deceive with respect to the misrepresentations and omissions regarding the motivations for revival.

## CONCLUSION

For the reasons stated above, the Court should affirm the judgment of noninfringement and affirm the exclusion of the untimely declarations. The Court should reverse the construction of the preamble as not limiting and reverse the judgment of no inequitable conduct.

Respectfully submitted,

Dated: March 12, 2014

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## CERTIFICATE OF SERVICE

I hereby certify, that on March 12, 2014, a true and correct copy of the Brief of Cross Appellants Soft Gel Technologies, Inc., and NOW Health Group, Inc., DBA NOW Foods, was caused to be served on the below-listed counsel by CM/ECF and electronic mail (by agreement of counsel):

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### **CERTIFICATE OF COMPLIANCE**

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief contains 13,000 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).
2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using MS Word in a 14 point Times New Roman font.

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